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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	DE 040071	7279

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 – 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Haim et al. (US 2002/0013615 A1).

Applicant should note that for the purposes of examination, Examiner regards the limitation "for the therapeutic embolization of aneurysms" as intended use, which does not limit the structure of the present invention in such a way that it is novel over the prior art. Applicant should further note that with respect to the active locator and locating device, "[determining the] spatial position and/or orientation of the catheter" also refers to intended use. Examiner makes the following rejection in light of this interpretation.

Regarding claims 1 and 3, Haim et al. discloses a catheter capable of injecting filler material by means of a pump (paragraphs [0020] and [0038]).

Regarding claims 2 and 4, Haim et al.'s device further comprises an active locator comprising a magnetic field sensor, for providing position and orientation of the catheter (paragraph [0021], first sentence; paragraph [0023]). A locating device (steering mechanism) is assigned to the catheter that works in connection with he active locator, and is capable of determining the position and orientation of the catheter (*paragraph [0021]*). In fact, as is known

in the art, as the steering mechanism steers the catheter, determining the spatial position and orientation of the catheter would be inherent to the steering process.

Regarding Claim 5, Haim et al. discloses a catheter, an electromagnetic locating device, and a pump device (please see rejections of claims 1 – 4).

Regarding claims 5 and 6, and with respect to the monitoring unit of the present application, Haim et al. discloses a monitoring unit (*control circuitry, **52***) that is capable of detecting the position of the catheter with respect to a biological entity, such as an aneurysm, and stopping or starting the injection of the fluid, or plugging material. The control circuitry contains storage space for storing a "road map;" and is designed to record measured position of the locator using the road map.

Applicant should note that control circuitry comprises a computer, which would inherently comprise a storage device capable of storing any type of information, including medical image data. (*paragraphs [0054 – 0075] and [0108 – 0111]*).

Regarding Claim 7, Haim et al. discloses, via incorporation of ***US 5,568,809*** (paragraph [0105]), that the apparatus of Claim 5 comprises an imaging device, such as X-ray, NMR, ultrasound, etc. (see US 5,568,809: col. 3, lines 43 – 60 and col. 5, lines 31 – 38).

Regarding Claim 8, please see rejection of Claim 5 with respect to the locating device.

Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Haim et al. discloses a locating device that works in conjunction with a magnetic field sensor device, then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. ***Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (US 2002/0013615 A1) as applied to Claim 5 above, and further in view of Bell et al. (US 2004/0091543).***

Regarding Claim 10, Haim et al. discloses an apparatus for the therapeutic embolozation of aneurysm, comprising components to inject a plugging material into the aneurysm.

Haim et al. differs from Claim 10 in that Haim et al. does not appear specifically to disclose that the plugging material comprises a curable polymer material, plastic beads, a plastic coil, a hydrogel and/or a fibrin sponge.

However, Bell et al. teaches the filling material may comprise cellulosic polymers (paragraph [0046]).

Accordingly, Bell et al. complements the disclosing of Haim et al. by teaching that therapeutic agents may be administered along with the plugging material (*paragraph [0047]*).

Therefore, it would have been prima facie obvious to combine Haim et al. with the teachings of Bell et al. to include cellulosic polymers, so that one could also administer therapeutic agents for additional benefits, to obtain the invention in the instant Claim 10.

2. ***Claim 11 is rejected under 35 USC 103(a) as being obvious over Haim et al (US 2002/0013615 A1).***

Regarding Claim 11, Haim et al. discloses a method of controlling the supply of a plugging material to a catheter, comprising a step of determining the position and/or orientation of the catheter via an active locator fitted thereon (*paragraphs [0111 – 0113]; and* ***fig. 3***).

Haim et al. differs from Claim 11 in that Haim et al. does not disclose speficially a step of automatically stopping the supply of the plugging material to the catheter if emergence of the catheter from the aneurysm is detected.

However, as Haim et al. explains, and would be obvious to one of ordinary skill in the art, providing this step for controlling the supply of material to the aneurysm would accomplished to avoid "possible systemic toxicity" (*paragraph [0112]*).

Accordingly, the evidence establishes that the method of intracardiac drug delivery that Haim et al. teaches is similar to the present invention in that Haim et al. teaches determining the position and orientation of the catheter is properly positioned in the desired area to ensure that the drug is administered properly in the correct location; and to stop the administration of the drug if the target area no longer requires the drug.

Therefore, it would have been prima facie obvious to modify Haim et al. to include a step of stopping the supply of the plugging material to a catheter if emergence of the catheter from the aneurysm is detected to avoid "deleterious effects," as Haim et al. puts it, to obtain the invention in the instant Claim 11

Regarding Claim 12, Haim et al. teaches that the position of the locator is recorded using a road map generated prior to the step of positioning of the catheter (paragraph [0110], see last sentence.

Regarding Claim 13, Haim et al. teaches, via incorporation of US 5,568,809 (mentioned in paragraph [0105]), that the catheter and the aneurysm are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent (US 5,568,809: col. 3, line 65 – col. 4, line 24).

Regarding Claim 14, Haim et al. teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11. Applicant should note that whether the area of the vascular system "outside the aneurysm" or not is irrelevant, because one of ordinary skill in the art would be aware that positioning of the catheter within the vascular system to avoid the aneurysm would

inherently involve utilizing positional data much the same way even if the catheter was positioned in an area well outside the aneurysm.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Garibaldi et al.* (***US 7,066,924 B1***) for method and apparatus for guiding a guidewire and catheter – using a magnet - through a body lumen for delivery of agents; and *Usami et al.* (***US 6,610,046 B1***) for catheter and guidwire used fro examination and treatement, such as embolization.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768